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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/311,720	05/14/1999	GREGORY M. GLENN	PM254809	1614

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EXAMINER
WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
1632	27

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Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary

Application No.	Applicant(s)
09/311,720	Glenn et al.
Examiner	**Art Unit**
Joseph Woitach	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Apr 23, 2003* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-127* is/are pending in the application.

4a) Of the above, claim(s) *32-34, 37, 38, 42, 43, 47-54, 59-71, 73, and 74* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-31, 35, 36, 39-41, 44-46, 55-58, 72, and 75-127* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This application is a continuation-in-pert of 08/749,164, filed November 14, 1996, now US Patent 5,910,306, which claims benefit to provisional application 60/086,196, filed My 21, 1998.

Applicants response filed April 23, 2003, paper number 26, has been received and entered. Claims 1-127 are pending and currently under examination.

Election/Restriction

Claims 1-127 are pending. Claims 32-34, 37, 38, 42, 43, 47-54, 59-71, 73 and 74 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species of the invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 21. Applicant has acknowledged the restriction requirement, and upon finding of generic claim allowable request rejoinder of withdrawn claims (Applicant's amendment page 2, first full paragraph). Applicant's request is noted, however a generic claim has not been found allowable.

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims drawn to an invention nonelected with traverse in Paper No. 21. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 1-31, 35, 36, 39-41, 44-46, 55-58, 72, 75-127 are under examination as they are drawn to the elected species (i) the antigen sequestrin; (ii) the adjuvant CpG1; and (iii) and adenoviral regulatory region for the expression of the antigen.

Priority

Applicant summarizes the Examiner's examination for the claim of priority and argue that the instant application is in compliance with the requirements of 35 U.S.C. 112, first paragraph, pointing to specific support in the previous parent applications for the claimed invention. See Applicant's amendment, pages 2-3. Applicant's response and arguments have been fully considered, but not found persuasive.

Initially, Examiner would agree that the pending application has support for the broad inventive concept of for methods of immunization. However, as noted in the previous office action, the basis for determining the priority of the invention under examination was the evaluation of all the specific elements recited and encompassed by the claims. In this case, the first teaching and support for the elected species of antigen sequestrin is in the provisional application of the instant application. Evaluation of the all the applications under 35 U.S.C. 112, first paragraph, would indicate that this is the first written description of the claimed

invention. The second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application) the disclosure of the invention in the parent application and in the second application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994). The invention of using sequestrin is first disclosed in application 60/086,196, filed My 21, 1998. Accordingly, because the elected invention is first described in the provisional application the instantly claimed invention presently under examination is given the priority date of May 21, 1998 (the filing date of the provisional application).

Information Disclosure Statement

The information disclosure statement filed April 14, 2003, paper number 23, fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

The claims are objected to because they encompass species which are not elected.

Examiner notes that in an election of species the amendment of the claims is not required pending the finding of an allowable generic claim. In the instant case, neither the generic nor the elected species has not been found allowable.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-31, 35, 36, 39-41, 44-46, 55-58, 72, 75-127 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of inducing an immune response in a mammal comprising the steps : providing a polynucleotide construct comprising an adenoviral regulatory region operatively linked to a polynucleotide encoding sequestrin; administering said construct to a mammal wherein administration results in the expression of said construct and production of a sequestrin protein, does not reasonably provide enablement for a method of immunization. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicant summarizes the initial burden of the office to question enablement of a claimed invention and summarize the basis of the rejection (pages 4-5). Applicant points out that the in

the scope of enablement rejection the office acknowledges that the method will result in an immune response and that the specification provides support for immune responses which may be therapeutic and that the limited meaning given to the term "immunization" is incorrect. Applicant concludes stating that "Prophylactic and/or therapeutic treatment is a preference; it is not an requirement" (Applicants amendment, top of page 5). Applicant argues that the working examples provide evidence that the antigen produce and immune response and that CpG is an effective adjuvant, and argue that based on these examples one could extend this to any antigen of interest (bottom of page 5). Applicant reviews each of ht cited references and argues that none of the teachings of the references provide evidence which is inconsistent with the claimed methods providing an immune response in a subject (page 6). Finally, Applicant argues that US Patent 6,310,046 has been issued with similar teachings, however claims (specifically claim 24) have been found enabled by the office and request Examiner to point to what teachings in the '046 patent is different from that provided in the instant specification (bottom of page 6). See Applicant's amendment pages 4-6. Applicants arguments have been fully considered, but not found persuasive.

Initially, Examiner notes that the specification does not define immunization but as pointed out by Applicant that an inducing an immune response may provide a treatment (Applicant's amendment, page 5). However, in this case because "immunization" is not specifically defined it has been given its plain meaning recognized in the art as providing a protective and/or prophylactic immune response. Applicants have pointed to literal support for

the assertion that an immune response may be therapeutic, with which Examiner does not disagree, however the claims do not recite inducing an immune response and specifically recite and encompass immunizing a subject. Therefore, while an induced immune response may be immunizing, Applicant has failed to point to portions of the specification or the art of record which would indicate that immunizing is simply a matter of inducing an immune response. Thus, contrary to Applicant's summary of the requirements of the claimed methods for method of immunizing not requiring or providing a protective or prophylactic affect, Applicant's arguments are not found persuasive because given the plain meaning of the term of "immunizing" the claims drawn to immunizing a subject would require providing a protective affect.

With regard to the cited references, Examiner would agree that none of the references teach that an immune response could not be generated or that sequestrin may be a candidate for the development of a vaccine against *P. falciparum*. However, as generally argued above for methods of immunization the references provide clear evidence that the immune response to sequestrin was not protective and thus, was not immunizing as required by the instantly claimed methods. At the time of filing of the instant application, providing antigens in the form of a DNA vaccine and the antigen sequestrin were known. Further, potential vaccines using sequenstrin were tried, however all were shown to be ineffective as vaccines and did not provide an immunizing effect even though they did induce an immune response. The teaching of the instant specification provides similar guidance and evidence, and no further guidance or evidence

wherein the claimed methods would result in any different affect in a subject. Thus, the teaching in the present specification does not provide the necessary guidance to overcome the art recognized limitations of immunizing with sequestrin serving as an antigen.

With respect to the teachings presented in US Patent 6,310,046 it is noted that each application is considered on it own merits. Importantly, with respect to claim 24, and other dependent allowed claims, it is noted that the methods of '046 and use of the products are drawn to a simple method of producing antibodies, not a method of immunizing a subject as presently claimed. In this case, it appears that the basis of the instant rejection is consistent with what was previously found enabled in the '046 patent.

As set forth above and in the previous office action, it is the lack of the necessary guidance for producing the prophylactic immune response considered by the art to be immunizing which is the basis of the enablement rejection. The courts have stated that reasonable correlation must exist between scope of exclusive right to patent application and scope of enablement set forth in patent application. 27 USPQ2d 1662 *Ex parte Maizel*. Scope of Enablement has been considered in view of the Wands factors (MPEP 2164.01 (a)). In view of the quantity of experimentation and the lack of direction or guidance provided by the specification to overcome the art recognized limitation for providing an immunizing affect, the absence of working examples for the demonstration or correlation that the claimed methods result in a protective immunizing affect in a subject, it would have required undue

experimentation for one skilled in the art to make and/or use the claimed inventions as broadly claimed. Therefore, for the reasons above and of record, the rejection is maintained.

Conclusion

No claim is allowed. As indicated in the previous office action, claims 1-31, 35, 36, 39-41, 44-46, 55-58, 72, 75-127 are free of the art of record. However they are subject to other rejections.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Joseph T. Woitach

Deborah Crouch

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PRIMARY EXAMINER
GROUP 1800/1630